EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF DR. DIONYSIOS K. VERONIKIS TVT

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure.

QUALIFICATIONS.

I, Dionysios K. Veronikis, MD, am fellowship trained with board certification in Female Pelvic Medicine and Reconstructive Surgery as well as general OB/GYN. I received my general Board Certification in Obstetrics and Gynecology in 2000 and my Sub-specialty Board Certification in Female Pelvic Medicine and Reconstructive Surgery in 2013 (first time certification was offered). Both certifications are active until December 2016.

A copy of my current curriculum vitae is attached to this report as Exhibit A.

I am a diplomat of the American Board of Obstetrics and Gynecology (ABOG), a fellow of both the American College of Obstetricians and Gynecologists (ACOG) and the American College of Surgeons (ACS). I am a member of the American Urogynecologic Society (AUGS), the Society of Gynecologic Surgeons (SGS), the American Association of Gynecologic

Laparoscopic Surgeons (AAGL), International Urogynecological Association (IUGA) and the International Continence Society (ICS). I have been awarded the Council on Resident Education in Obstetrics and Gynecology "Teacher of the Year" by the resident staff of the Massachusetts General Hospital and the Brigham and Women"s Hospital in 1997 and by the resident staff of St. John"s Mercy Hospital in 2002. I have won the Society of Gynecologic Surgeons First Prize Fellow Research Award in 1996 and 1997.

I received my BS in Biology and Experimental Psychology from Moravian College in Bethlehem, Pennsylvania in 1982 and graduated with an MD from the University of Patras School of Medicine and Allied Health Sciences in Patras Greece in 1988. I did my internship in General Surgery at Morristown Memorial Hospital in Morristown, New Jersey from 1990 to 1991 and my residency in Obstetrics and Gynecology from 1991 to 1994 at Baystate Medical Center in Springfield, Massachusetts. I was a fellow in Vaginal Surgery and Urogynecology at the Massachusetts General Hospital, Harvard Medical School in Boston, Massachusetts from 1994 to 1997 under the mentorship of Dr. David Nichols.

Since 1997 I have been the Chief of Gynecology and Director of Vaginal Reconstructive Surgery and Urogynecology at St. John"s Mercy Medical Center in St. Louis, Missouri. In this capacity I am responsible for training the general OB/GYN residents in Vaginal Surgery and Urogynecology in the clinic, the classroom and the operating room. In 2003 I became the Program Director for the Obstetrics and Gynecology Residency Program at St. John"s Mercy Medical Center.

I have been a visiting surgeon across the United States and to Europe visiting Parma, Italy; University of Liege, Belgium; Kent, England and Madrid, Spain.

My surgical practice has exclusively focused on Vaginal Reconstructive Surgery and Urogynecology since 1994 with an annual case load that I estimate exceeds 600 cases annually. I estimate that I have personally performed nearly 10,000 vaginal reconstructive surgeries for incontinence and pelvic organ prolapse and I have implanted thousands of mesh products. I have cared for women from 49 states across the United States, four Canadian Provinces and four continents.

I am extremely familiar with the injuries and problems associated with the transvaginal mesh products from the thousands of patients I estimate I have examined and treated as these women present for evaluation and treatment. I have reviewed volumes of patient‟s medical records that has allowed me to reliably correlate the symptoms and complications that develop from mesh placement and to develop a differential diagnosis that is consistent and supports my observations and opinions and confirms my surgical findings at the time of mesh revision/removal. I have revised/removed many mesh products for mesh complications that include but are not limited to mesh erosion, exposure, apareunia, dyspareunia, pelvic pain, and hip or leg pain. I have a vast and global experience with mesh removal, including retropubic, suprapubic, transobturator and single incision slings and anterior and posterior mesh from American Medical Systems, Boston Scientific, Ethicon, Bard, Coloplast, Caldera, Mentor and Tyco.

I have significant surgical experience encompassing the breadth and depth of vaginal reconstructive pelvic surgery including for primary, recurrent as well as transvaginal mesh removal surgeries.

My first experience with vaginal mesh used to treat pelvic floor defects was in 1994, during my fellowship with Dr. David Nichols when I trained in Boston.

I estimate that I have personally examined, diagnosed and treated over a thousand patients with mesh complications. Currently, I devote half my surgical referral practice to treating vaginal mesh complications.

I estimate that have revised/removed over a thousand vaginal mesh products including transvaginal mesh slings (including Gynecare"s TVT) and prolapse mesh kits and in 2015 alone I surgically removed 296 mesh implants**.**

Based upon my clinical work as a vaginal surgeon, urogynecologist and pelvic floor reconstructive surgeon, I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis, and treatment of patients suffering from complications caused by pelvic mesh implants. The most common mesh related complications include vaginal mesh exposure/extrusion through the vaginal epithelium, mesh erosion into the rectum, bladder, and or urethra, acute and chronic vaginal and pelvic pain, apareunia, dyspareunia and nerve damage.

I am familiar with the Ethicon TVT device ("TVT") specifically, as contrasted to other anti-incontinence mesh products and mesh in general. I have seen video regarding implantation of the TVT, read clinical literature, and handled the TVT product. I have personally removed TVT mesh. I know this from the medical history and medical records of the mesh patients I explant.

In offering the opinions set forth in this report, I rely upon a review of Ethicon documents and depositions, the medical literature, and my background, training and extensive career experience in vaginal surgery, and at managing mesh complications. I hold all these opinions to a reasonable degree of medical certainty.

OPINIONS

In general, my expert opinions can be summarized as follows[1]:

A. The mesh used in the TVT (Prolene) is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence because the pores are too small, it is not light weight, causes chronic foreign body reaction and inflammation, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, has sharp edges, ropes, curls and deforms.

B. Ethicon knew that the old construction, mechanically cut mesh (Prolene) was not appropriate for use in its TVT device but has failed to modify/change the mechanically cut mesh to a larger pore, lighter weight mesh that would not deform, fray, lose particles, rope, curl, degrade, cause excessive foreign body reactions, and cause excessive shrinkage or contraction;

C. Ethicon failed to adequately describe, inform or explain to physicians how to properly "tension" the TVT; the mesh shrinks, contracts, ropes and curls making it difficult or impossible to tension in a safe manner for patients;

D. Ethicon‟s TVT Instructions for Use ("IFU") are inadequate based on Ethicon‟s failure to include warnings about the adverse reactions and risks caused by the TVT that were known to Ethicon or which Ethicon should have been aware, or misstated or failed to disclose the frequency, severity and duration of risks.

E. Ethicon failed to inform physicians that certain patient populations may be more prone to experience adverse outcomes and higher frequency or severity of risks.

F. The benefits of the TVT are outweighed by the serious complications associated with the device, and there were safer alternative options available.

Overview of Stress Urinary Incontinence

Stress urinary incontinence is the most common type of incontinence found among women and generally occurs after pregnancy, childbirth, prior pelvic operations, and aging. It occurs when the pelvic floor tissues and muscles that support the urethra and bladder weaken, leading to urethral hypermobility. The pre-dominant symptom is involuntary loss of urine during physical activities such as coughing, sneezing, laughing, running, jumping, or any other activity where there is an increase in abdominal pressure.

Non-Surgical Treatments for Stress Urinary Incontinence.

There are many non-surgical options available to treat SUI in women, such as:

1. Behavior Modifications – including exercise, weight loss, reduced intake of alcohol and caffeine, proper dietary and fluid management, and smoking cessation.
2. Pelvic Floor Muscle Training – including Kegel exercises, pelvic floor physical therapy, weighted vaginal cones, and biofeedback mechanisms.
3. Devices and Absorbent Products – including pessary, urinary inserts and seals, absorbent pads and panty liners.
4. Bulking Agents – injections into the tissues surrounding the urethra that aid in bladder support and tightening of the bladder neck reducing urine loss.

Surgical Options for Stress Urinary Incontinence.

There are many surgical procedures with their own variations that have been used to treat SUI including:

1. Retropubic Urethropexies – such as Burch and Marshall-Marchetti-Krantz
2. Needle Bladder Neck Suspensions – such as Raz and Stamey

3. Suburethral plication with anterior repair

4. Pubovaginal Slings – using autologous, allograft, xenograft, or synthetic materials

The mid-urethral tension free tape was introduced during the mid-1990‟s by Ulmsten.[2] Since then, a number of techniques and various sling products have been introduced and used under the general term Mid-Urethral Slings ("MUS").

While numerous publications purport to address efficacy and safety of the MUS, analysis of those publications indicates that most of them do not address long-term or even mid-term safety, or are not of the level of evidence upon which physicians normally rely. For example, the TOMUS review[3] is often cited as showing that MUS are safe. However, the article states "there are currently no adequately powered trials with sufficient length of follow-up comparing the efficacy or safety of transobturator and retropubic MUS…New surgical therapies for the treatment of SUI are developed and offered as standard of care without adequate scientific evaluation of their effectiveness or safety." Similarly, another article reports "complication rates within 1 year after the sling surgery…were found to be higher than those reported in the clinical literature…although slings, along with the Burch colposuspension, are considered the gold-standard in management of SUI, few rigorous health service research studies have been published that evaluate patient outcomes after sling surgery and other procedures for SUI…A systematic review of the literature identified a number of methodological flaws in published series, including a lack of comprehensive assessment of post-operative complications."[4]

The TVT is defectively designed.

Stress urinary incontinence ("SUI"), the condition TVT was sold to treat, is not painful or dangerous to the patient‟s health. There are several other procedures, surgeries and products

available to treat this lifestyle disorder. Any benefits that Ethicon believes are attributable to the TVT are outweighed by the risks of the device, which are discussed below.

Before introducing a medical device for permanent implantation by doctors such as myself, doctors have an expectation that that the manufacturer will analyze the risks of the product and consider those risks in light of any benefits that the manufacturer believes the design of the product would provide. Doctors also expect that the manufacturer will have considered the duration of any anticipated risks, as well as their effects on the patient and how any complications may be treated. It is possible that the cure can be worse than the disease, so it is important for doctors to be informed about addressing complications before putting products in our patients. When the complications associated with a product are serious and potentially life altering and permanent, the benefits would have to be significantly greater than the risks in order to justify the use of that product.

The original Prolene mesh used in the TVT is "heavyweight" and "small pore" and "microporous" by Ethicon"s own internal definition.[5] This type of mesh design results in excessive scar plate formation, which can lead to vaginal deformation and can damage and entrap nerves, and lead to long-term or life-long pain.[6]

As recognized in internal Ethicon documents dating back decades, the Prolene mesh used in the TVT was "far from" ideal for use in the vagina.[7] The polypropylene material itself creates an intense and chronic inflammatory response, and is prone to shrinkage due to tissue reaction.[8] Ethicon had other materials available for use in the TVT which were safer than polypropylene.[9]

Ethicon"s Head of Preclinical, Dr. Jorge Holste, testified that Ethicon developed lighter weight, large pore meshes in order to minimize the complications seen with heavyweight meshes like the Prolene used in TVT.[10] Ethicon employee, Christophe Vailhe, testified that

there can be an excessive inflammatory reaction or foreign body reaction that would lead to mesh erosion and contraction.[11]

When the tissues surrounding the mesh shrink, this can entrap nerves and deform the surrounding tissues, and cause severe and chronic pain.[12]

The force required to implant the TVT with the metal introducers deforms the mesh, and the mesh can also deform after implantation as in vivo forces are exerted on the sling.[13] The design of the TVT trocar size, arc/handle, width and the TVT mesh is a design mismatch for the pelvis as well as for the delivery of the TVT mesh. The puncture created by the TVT trocar with an imperfect circular tissue penetration forces the TVT mesh to deform with implantation with immediate curling. The deformation of the TVT mesh impairs tissue ingrowth and contributes to the excessive scarification and contraction of the mesh and resulting pain, and can also lead to complications like erosion and urinary retention.

The mechanically cut mesh used in the TVT was known to rope, curl and deform when under tension.[14] The "mechanical cut" version of mesh used in the TVT could "fray" or release particles upon or after implantation, causing the mesh to change shape and add to the inflammatory response to the material.[15] In an April 2006 Clinical Expert Report on Laser Cut Mesh, it was suggested that the decrease in particle loss with laser cut mesh "would lead to less non-functioning material left in the tissues."[16] According to an internal Ethicon risk analysis, the risks associated with curling/roping, frayed edges, and inadequate pore size of the mechanically cut mesh can lead to erosion, recurrence and pain.[17] Ethicon Quality Engineer, Dan Lamont, agreed in his deposition that Ethicon continued to sell "mechanically cut mesh despite knowing that it had the potential for degradation, particles floating around in women"s bodies, stretching,

and roping…."[18] Mr. Lamont further explained that the mesh "fraying," which he explained was "those loose ends starting to come apart," "is a defect."[19]

An internal memo relating to Ethicon's tensile strength testing reported that laser cut TVT was approximately three times stiffer than the mechanical cut mesh at 20% elongation.[20] The stiffer mesh construct was associated with adverse outcomes, including difficulty achieving proper tensioning, and pain, damage or impingement to the urethra, and bladder damage.[21]

Any surgical attempt to remove mesh implanted transvaginally after complications arise increases the presence of scar tissue, which can cause or exacerbate the patient's pain, dyspareunia and deformation of vaginal tissues and abnormal function of that pelvic area. Even though it is difficult to remove all of an implantable SUI sling like the TVT, I have not seen evidence to suggest that Ethicon ever considered what should be done if the mesh caused complications and had to be removed, or how to remove the product.

Ethicon failed to adequately warn physicians and patients about known problems with the TVT.

As an active explanting surgeon of the TVT device, I have reviewed and I am familiar with the Instructions for Use, Physician Training materials, and sales and marketing materials prepared by Ethicon for the TVT. I have also reviewed the IFUs for many other medical products that I have implanted and explanted in patients during the 19 years I have been practicing vaginal surgery, urogynecology and pelvic reconstructive surgery.

In order to make an informed decision as to whether to use a particular product in a given patient, a reasonable physician would expect a medical device seller to provide all pertinent information known to the company that could impact a reasonable physician's decision

to use that product. Failure to provide physicians with relevant information that is known to the manufacturer bearing on the potential safety of a product prevents physicians from making informed decisions about whether to utilize the product. This failure also prevents physicians from properly counseling patients in considering whether to consent to permanent implantation of the medical device.

It is also incumbent upon a manufacturer to tell users of its products if a particular complication or adverse event can be chronic, severe or permanent. Meng Chen, Ethicon's Associate Medical Director for Worldwide Quality, urged the company to amend the TVT IFU because "[o]ur post-market knowledge with these products are much more than what we have in the IFUS of all three types of TVTs,"[22] and also expressed concern that any reference in the TVT IFU to certain identified complications as "transitory" is inadequate, and stating that "from what I see each day, these patient experiences are not „transitory" at all."[23] As Ms. Chen explained to Ethicon's upper management, "[o]ne of the paths for a better pre-operative consent is to provide an updated IFU to the operating physicians that reflect[s] the current knowledge of the manufacturers on the potential adverse reactions."[24]

In her January 29, 2009 email, Meng Chen wrote that the IFU should be updated to make it clear that the irritation and foreign body response were a result of the tape itself and that this "could result in tape extrusion, tape erosion, fistula formation or inflammation."[25] When working on an IFU for a subsequent SUI sling product, Ethicon employees noted that the older IFUs should be updated. Dr. Aaron Kirkemo wrote:

> I would agree from the meeting today that now that we have 12+ years of experience with TVT classic that learnings from the field would probably drive a relook at the TVT Classic IFU as reflected by some of your comments in this document.[26]

Ethicon Medical Director David Robison responded: "has there been agreement re: a project to revise TVT and TVTO?"[27] There was no revision to address these risks, at least not until 2015: "Per Scott C and Stale, they just want to "look forward" with this project. Their plans are to leave TVT Classic as is. Aaron."[28]

The TVT IFU contains several statements that, in my opinion, are misleading because they contradict information known or at least available to Ethicon, according to Ethicon‟s own documents.

The IFU states that "[t]he material [in the TVT mesh] is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes." However, contrary to this statement, Ethicon‟s internal documents reflect that the polypropylene material used in the TVT mesh was subject to degradation inside the body.[29]

Ethicon‟s documents reflect that the polypropylene material used in the TVT device causes an "excessive" and "chronic" foreign body reaction and "intense" and "chronic" inflammation,[30] which contradicts the IFU statement that "[a]nimal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient…."

There were numerous serious safety risks associated with the TVT that have never been included in the TVT IFU, including: voiding dysfunction; acute and/or chronic pain; painful intercourse that may not resolve; one or more revision surgeries may be necessary to treat adverse reactions; the mesh is a permanent implant and significant surgery may be required if the mesh needs to be removed; urge incontinence; urinary frequency; urinary retention; adhesion formation; bleeding; dysuria; atypical vaginal discharge; exposed mesh may cause discomfort to

a sexual partner during intercourse. These risks were not included in the TVT IFU until the IFU was apparently amended in 2015 to address these risks.[31]

There was never any warning provided that the polypropylene material used in the TVT mesh causes intense, chronic and excessive inflammation and foreign body reaction, and is susceptible to degradation, which perpetuates the inflammation and foreign body reaction.

Ethicon never provided any warning to address the risks associated with the deformation of the TVT mesh upon and after implantation, including the curling and roping of the arms, which could cause or exacerbate the shrinkage and associated pain. The IFU outlines an implantation approach that deforms the TVT mesh upon implantation.

Ethicon failed to warn that the TVT was susceptible to shrinkage inside the body due to tissue response, and failed to warn that this contracture was associated with deformation of the mesh which can cause pain.[32] No warning was provided about how often this shrinkage and deformation could occur, or the severity of the complications associated with this risk.

Ethicon"s internal documents and employees acknowledge that the minimum pore size of mesh must be greater than 1 mm after implantation in order to allow tissue ingrowth and to avoid excess scar plate formation.[33] The pore size of the Prolene mesh used in the TVT device was significantly less than 1 mm.[34] Ethicon never warned any patient or doctor about the increased risks of excess scarring inherent in the product"s design.

There was no warning provided about the risks of nerve damage, nerve entrapment, nerve tethering or nerve severing caused by the TVT mesh after implantation.[35]

Ethicon never warned about the potential for mesh fraying with the mechanically cut TVT.

Ethicon failed to warn about the risk of stiffness and resulting pain associated with the laser cut TVT mesh.

Ethicon failed to warn about the difficulty of removing the TVT mesh in its entirety once it is implanted.

Ethicon did not provide any warning to physicians or patients that the surgical procedures necessary to remove mesh can themselves cause serious, long-term complications.

Ethicon failed to provide any instruction or direction as to how to address complications, or what to do in the event that mesh removal was necessary. In fact, before the TVT was sold, Ethicon‟s internal documents reflect concern that providing instruction or direction regarding removal of their mesh would cause physicians to worry that mesh removal could be necessary, and indicate concern that "overinformation" about mesh removal would be "digging my own grave."[36] No warning was provided that surgical intervention may not relieve the symptoms associated with the TVT.

Even if Ethicon did not have knowledge of the information about a risk at the time the TVT was first sold, once this information became available, the company should have made changes to the IFU and otherwise made reasonable efforts to ensure that physicians continue to have the information necessary to make informed and safe treatment decisions for patients. Ethicon changed the IFUs for the TVT but never provided any of the information above.

If Ethicon knew or believed that there may be risks specifically associated with the use of its TVT product in any given category of patients, it was obligated to so advise the physician users of the products. Ethicon failed to provide any warning or contraindication that the TVT was not an appropriate treatment for any category of patients other than women who are

pregnant or may become pregnant, women on anticoagulation therapy, and women who have a urinary tract infection.

I reserve the right to amend, supplement, or alter my opinions in this report as additional materials, documents, and deposition transcripts become available.

DATA CONSIDERED IN FORMING MY OPINIONS

I considered the documents identified in the body and footnotes of this report, as well as those listed in Exhibit B attached hereto.

EXHIBITS WHICH I PLAN TO USE AS A SUMMARY OF OR IN SUPPORT OF MY OPINIONS

I may use documents that I reviewed and which are identified above, female pelvic floor models and illustrations, samples of the TVT, and summaries of literature that I may prepare.

COMPENSATION FOR MY REVIEW, STUDY AND TESTIMONY

I charge $1,000 per hour for review and study of records. I charge a 50% premium on records that must be reviewed within 30 days. Deposition fees are $6,000 per half day and $10,000 per full day. Court appearances are $10,000 per day.

OTHER CASES IN WHICH I HAVE TESTIFIED AS AN EXPERT AT TRIAL OR BY DEPOSITION IN THE LAST FOUR YEARS

Linda Fisher, et al. v. Boston Scientific Corporation
Case No. 2:13-cv-29324
United States District Court for the Southern District of West Virginia
11/24/14

Tracy Reynolds v. Boston Scientific Corporation
United States District Court for the Southern District of West Virginia
Case No. 2:12-cv-09934
11/24/14

In re: Boston Scientific Corp. Pelvic Repair System Products Liability Litigation
United States District Court for the Southern District of West Virginia

Wave 1 and 2 Cases
Case No. 2:12-md-02326
1/5/15

Candy Young, et al v. Boston Scientific Corporation
United States District Court for the Southern District of West Virginia
Case No. 2:14-cv-08929
1/24/15

Rae Lynn Herpich, et al. v. C.R. Bard, Inc.
United States District Court for the Southern District of West Virginia
Case No. 2:13-cv-29274
2/10/15

*Chelsea Stewart and Matt Stewart V. Boston Scientific Corp*oration
United States District Court for the Southern District of West Virginia
Case No. 2:12-cv-03686
6/13/15

Bobbie Jo Woolf v. Mentor Worldwide LLC
United States District Court for the Middle District of Georgia
Case No. 4:12-cv-00252
9/5/15

Frances McBride v. Mentor Worldwide LLC
United States District Court for the Middle District of Georgia
Case No. 4:12-cv-00249
9/5/15

Dionysios Veronikis, M.D.

1-25-16
Date

CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2016, I served the **PLAINTIFFS' RULE 26(a)(2)(B) EXPERT REPORT OF DIONYSIOS VERONIKIS, M.D.** on the following counsel of record by electronic mail:

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[1] This is not intended to be an exhaustive recitation of my opinions in this case. The full scope of my opinions are described in further detail in this report.

[2] Ulmsten U., Henrikkson L., Johnson P., Varhos G. *An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence.* Int Urogynecol J (1996) 7:81-86.

[3] Urinary Incontinence Treatment Network. *The Trial of Mid-Urethral Slings (TOMUS): Design and Methodology.* The Journal of Applied Research. Vol. 8, No. 1, 2008;Richter HE, Albo ME, Zyczynski HM, et al. *Retropubic versus transobturator midurethral slings for stress incontinence.* N Endl J Med 2010;362:2066-76.

[4] Anger J, Litwin M, Wang Q, Pashos C, Rodriguez L. *Complications of Sling Surgery Among Female Medicare Beneficiaries.* Obstet Gynecol 2007;109:707-14.

[5] ETH.MESH.05920616 (7/20/07 internal e-mail) – "Ethicon's definition of Lightweight is as follows: - Large pore size > than xx mm (varies from 1,5 mm - 5 mm)… We use this definition for all our meshes."). ETH.MESH.05479535 (5/30/11 Ethicon chart identifying TVT mesh as "microporous").

[6] ETH.MESH.00680021 (11/12/08 internal e-mail) – "The standard polypropylene mesh may in fact be over-engineered or too strong. The body‟s reaction to dense or heavyweight meshes results in intense inflammation and mesh shrinkage…. Polypropylene creates an intense inflammatory response that results in rapid and dense incorporation into the surrounding tissue. The excessive inflammatory reaction caused by heavyweight meshes tends to form a scar plate around the prosthetic that results in a firm and contracted mesh."); ETH.MESH.02247342 (1/21/09 internal PowerPoint) "Importance of Pore Size. Polypropylene creates an intense inflammatory response that results in rapid and dense incorporation into the surrounding tissue. The excessive inflammatory reaction to heavyweight Polypropylene tends to form a scar plate around the prosthetic that results in a firm and contracted mesh…Bridging occurs in all mesh modifications with a granuloma size around each mesh fiber exceeding more than half to the pore size of the mesh. Desirable pore size >1mm. [citing literature from 2005 and 2006]."); ETH.MESH.05479695 (Nov. 3-4, 2010 Mesh and Textile Summit PowerPoint) – "There is no place for a „Heavyweight Mesh‟ in modern pelvic floor repair… Polypropylene Mesh – Small pore size (<1 mm)… Downsi[d]es of „old fashioned‟ mesh – Excessive foreign body reaction – Chronic inflammation – Decreased fibrocollagenous ingrowth – Scar plate formation – Shrinkage from bridging fibrosis – Stiffness-soft tissue restriction…. Issues with small pore meshes – Formation of connective tissue correlates with degree of inflammation, but does not translate to strength – Increased inflammatory response results in rigid scar plate formation – Scar plate responsible for shrinkage of mesh up to 40% [citing published literature from 2002 and 2004].").

[7] ETH.MESH.12009030 – (8/18/98 internal e-mail) – "PROLENE [was] far from being the ideal material for this [gynecologic] indication."); ETH.MESH.11283974 – (5/3/99 internal e-mail) –

"Prolene mesh seen as a very weak point of the TVT."); ETH.MESH.03904451 (6/06/00 internal memo) – Disadvantages of Prolene/Gynemesh: "Too thick and bulky, too stiff…. The in vivo forces and exerted strains on pelvic floor repair during the postoperative period are not known. No studies on this subject were identified through literature search or interviews with experts.").

[8] ETH.MESH.13375497 (10/1/08 internal PowerPoint) – "Issues with Polypropylene Mesh • Excessive foreign body reaction • Chronic inflammation…• Scar plate formation • Stiffness…• „Shrinkage" 20-40%.").

[9] ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) ("Polypropylene meshes might not be improvable in terms of shrinkage, we may need a completely new material… Unmet clinical needs: No shrinkage/no long term contraction… Severe contraction –> Dyspareunia –> sexual function ↓."); HMESH_ETH_02860031 (7/06/07 internal e-mail from Ethicon Research Fellow regarding prior "dog" study) – "I recall the long-term dog study did show some „fibrillation" of PROLENE suture where none was observed for PRONOVA suture. My polymer colleagues tell me that PP has the potential to do this because of its molecular structure."); ETH.MESH.00857704 (2/12/09 internal e-mail regarding development of potential new mesh product constructed of PVDF "Pronova") – "I think we have multiple advantages over +M like:…If we use PRONOVA a more elastic fiber which show less degradation than PP. Better, longer function of Implant."); HMESH_ETH_00228962 (2/17/10 internal e-mail chain discussing polypropylene literature) – "[W]e know from literature that polyester and even polypropylene tend to alter over time in the body…. [H]ow has the general surgery group responded to this [degradation literature]?...[W]e proposed for several new product developments...to use PVDF or PRONOVA as a more stable filament, however Senior Management decided to go ahead with PP as a standard." (HMESH_ETH_00228961)).

[10] Holste depo. (7/29/13), 51:3-53:6.

[11] Vailhe depo. (6/21/13), 383:8-19.

[12] Smith T, et al., Pathologic Evaluation of Explanted Vaginal Mesh: Interdisciplinary Experience from a Referral Center. Female Pelvic Med Reconstr Surg 2013; 19:238-41; Klosterhalfen, et al., The Lightweight and Large Porous Mesh Concept for Hernia Repair. Expert Rev. Med. Devices 2(1) 2005; Castellanas ME et al., Pudendal Neuralgia After Posterior Vaginal Wall Repair with Mesh Kits: An Anatomical Study and Case Series. Journ Minimally Invasive Gynecol 19 (2012) S72. 73); Heise, C. P., et al. (1998). Mesh inguinodynia: a new clinical syndrome after inguinal herniorrhaphy? Journal Of The American College Of Surgeons, 187(5), 514-518; Demirer, S., et al. (2006). The effect of polypropylene mesh on ilioinguinal nerve in open mesh repair of groin hernia. The Journal Of Surgical Research, 131(2), 175-181. ETH.MESH.05631478 (8/16/02 internal e-mail discussing article describing mesh-related nerve injury – ("In the post retrieval study most explants of all patients with chronic pain in their history indicate nerve fibres and fascicles in the interface of the mesh. Today, immunohistochemical stains relieve even the detection of smallest nerve structures which are mainly found in the foreign body granuloma. Due to the nature of the granuloma as a chronic inflammation it may be speculated that these nerve structures are irritated by the inflammation and cause the sensation of pain"); ETH.MESH.05455878 (1/18/03 Ethicon Surgeon Panel

meeting notes) – Ethicon surgeon advisor told Ethicon "Some rate of long term risk to humans of…nerve entrapment with chronic pain…often the result of tiny nerves in the granuloma…even if you care for the big nerve you can't prevent pain."); HMESH_ETH_00343700 (7/6/06 internal document commenting on published article) ("in the authors' postrieval study the involvement of nerve fibers was found in more than 60% of all mesh specimens removed due to chronic pain."); HMESH_ETH_01801001 (10/11/06 internal e-mail re: published article) – "The article highlights that 60% of pain related issues in hernia repair are contributed to disturbance with nerve."); HMESH_ETH_00144721 (2/11/08 internal e-mail) – "Peripheral nerve irritation following synthetic mesh implantation can be implant-related or procedure-related. Implant-related factors include foreign body tissue reaction, fibrotic tissue response and shrinkage."); ETH.MESH.13375497 (10/1/08 internal PowerPoint) (Regarding mesh-related pain "The tissue reaction at the mesh implant is like a chronic wound, present for years and years after the implantation," and studies of explanted meshes show "Nerve fibers and fascicles in the interface of the mesh…The nerve structures are irritated by the inflammation an cause sensation of pain.").

[13] ETH.MESH.00442080 (1/7/05 internal e-mail "Confirmation of the Improved TVT (Mesh) Rationale (Draft)") – "It is acknowledge that there is a gap with our TVT product with both sheath removal and Mesh construction {Fraying/Deformation through stretching (roping effect)}. These issues are interrelated as much as the sheath removal may cause the mesh to stretch or move causing the physician to further stretch the mesh resulting in the deformation."); ETH.MESH.01822361 (10/18/06 internal e-mail) – "The Laser cut mesh of TVT SECUR has less potential to cause retention than TVT or TVT Obturator because the tape will remain flat under the urethra. TVT and TVT Obturator would curl and rope which reduces the surface area of the mesh."); ETH.MESH.07396540 (11/02/06 internal communication) – "Traditional GYNECARE TVT will narrow and curl when pulled, thus it may become smaller than the hole made by the GYNECARE TVT needle, thus pulling out easily.").

[14] ETH.MESH.08334245 (internal Ethicon presentation containing photographs showing particle loss, roping and mesh deformation with mechanically-cut mesh when compared with laser-cut mesh).

[15] ETH.MESH.03904451 (6/06/00 internal memo), p. 4454 – "Disadvantages [of Prolene/Gynemesh]: "releases particles when cut….", p. 4466 – "small particles are released that migrate through the vaginal wall causing pain during intercourse"); HMESH_ETH_00958017 - "It is true that fraying is inherent with the current [TVT] construction."); HMESH_ETH_00958313 - "Attached please find the report and data files from a comparative investigation of the release of particulate from clear and blue mesh. The report indicates that the amount of particulate released is the same for the clear and blue mesh."); ETH.MESH.06212843 – "first, if it does not fray, we should say so. If it splits and splinters, would that appear as a fray? Why have we received all these reports of Prolene fraying if it does not fray?"); ETH.MESH.00541379 – Memo from Gynecare Sr. Med. Director stating, in part: "Fraying is inherent in the design and construction of the [TVT] product. The application of tension exacerbates this issue. When the mesh frays, several events occur: the mesh elongates in places; the mesh narrows in places; and small particles of Prolene might break off.");

ETH.MESH.00863391 – internal e-mail addressing complaints of mesh particles and embrittlement, Ethicon employee states: "This is not new, and was exactly the original issue that stopped TVT blue for months... I believe that the board has to set a directive that can be filtered down to the reps, saying its OK and its not an issue, same as TVT clear except you can see it... This is not going away anytime soon and competition will have a field day, major damage control offensive needs to start to educate the reps and surgeons UPFRONT that they will see BLUE shit and it is OK. This is why I wanted to launch TVTO in clear!!!!!.").

[16] ETH.MESH.00167104, p. 7109.

[17] ETH.MESH.01218019 (2006 Ethicon dFMEA).

[18] Lamont depo. (9/11/13), 30:18-24.

[19] Id., 15:16-16:10.

[20] Robinson depo. (7/25/13), 507:18-508:1; Id., 509:6-21. See also, ETH.MESH.00302181 (March 2006 internal testing results showing less elasticity of laser cut mesh: "MCM meshes stretch between 55.8% and 33.4%. The LCM meshes stretch between, 39.5% and 32.1%.").

[21] ETH.MESH.04048515, p. 8516 (7/1/08 KOL interview with Carl G. Nilsson (founder of TVT) stating he "will not use Laser-cut mesh!!" because it "does not have the same stretch profile of Mechanical-cut mesh."); ETH.MESH.01218019 (dFMEA for Laser Cut Mesh) (noting if mesh too stiff, it can lead to "Harm: Pain, Damage to Urethra, Urethral Impingement, Damage to Bladder.").

[22] ETH.MESH.04092868 (12/19/08 internal e-mail).

[23] ETH.MESH.04094863 (1/29/09 internal e-mail).

[24] ETH.MESH.04092868.

[25] ETH.MESH.04094863 (1/29/09 internal e-mail).

[26] ETH.MESH.01239065 at 9066 (7/14/09 internal e-mail from Aaron Kirkemo MD to Piet Hinoul MD and David Robinson MD).

[27] Id.

[28] Id.

[29] ETH.MESH.00870467 ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) – "Prof. Cosson questions if Polypropylene is the best material as fractures are observed in pp [sic] after time."); HMESH_ETH_02860031 (7/06/07 internal e-mail from Ethicon Research Fellow regarding "dog" study) – "I recall the long-term dog study did show

some „fibrillation" of PROLENE suture where none was observed for PRONOVA suture. My polymer colleagues tell me that PP has the potential to do this because of its molecular structure."); ETH.MESH.05588123 (7/09/07 internal memo responding to mesh degradation literature) – "There have been a number of anecdotal reports that PP mesh shows some changes in the surface with time. The Aachen group, who has so far collected more than 1000 explanted meshes, showed examples many years back…. We did different tests in-house with accelerated aging, too, and found microscopic changes in the surface of mesh fibres."); HMESH_ETH_00228962 (2/17/10 internal e-mail chain discussing polypropylene degradation literature) – "[W]e know from literature that polyester and even polypropylene tend to alter over time in the body…. [H]ow has the general surgery group responded to this [degradation literature]?...[W]e proposed for several new product developments...to use PVDF or PRONOVA as a more stable filament, however Senior Management decided to go ahead with PP as a standard." (HMESH_ETH_00228961)); ETH.MESH.10578304 (1/18/11 Minutes of PA Consulting Group Meeting regarding Mesh Erosion) – "PP meshes degrade over time following implant; this is observed at very high magnification (using electron microscopy) as „fractures" in the surface of the extruded fibres which cause particulates of PP to be produced which can break away from the main fibre."); ETH.MESH.14445346 (1/17/12 PowerPoint), Slide 11 (comparing Polypropylene to PVDF) – "PP – Stress cracking after 2 years of implantation [citing Mary article from 1998]… PP – In vivo degradation of PP [citing Clave article from 2009]."); ETH.MESH.07726993 (3/12/12 Ethicon internal memo in response to article reporting polypropylene mesh degradation) – "In an infected field and/or a site of chronic inflammation, it is not unexpected that there will be an increase in free radicals and other reactive oxygen species. Polymers may be subject to surface degradation by these reactive species, the impact of which has not been clinically assessed.").

[30] ETH.MESH.05455879 (1/18/03 notes from Surgeon Panel Meeting) - "Polypropylene - initial acute inflammation then chronic foreign body reaction."); ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) ("Polypropylene meshes might not be improvable in terms of shrinkage, we may need a completely new material…."); ETH.MESH.00271215 (10/29/08 internal e-mail) – Polypropylene is "the best of a bad lot re integration/retraction" and "there is a need to develop grafts that mimic the human tissue mechanical properties."); ETH.MESH.00680021 (11/12/08 internal e-mail) – "Polypropylene creates an intense inflammatory response that results in rapid and dense incorporation into the surrounding tissue. The excessive inflammatory reaction caused by heavyweight meshes tends to form a scar plate around the prosthetic that results in a firm and contracted mesh."); ETH.MESH.03722384 (9/17/09 internal e-mail) – "We're seeing a lot of work published that indicates that polypropylene produces an ongoing, chronic inflammatory reaction…Might be better off working with something that is less reactive, like PVDF."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering.""); ETH.MESH.05237872 (Nov. 3-4, 2010 "Mesh and Textile Summit") – PowerPoint addressing downsides of "old fashioned" (i.e., polypropylene mesh): "Excessive foreign body reaction; Chronic inflammation; Decreased fibrocollagenous ingrowth; Scar plate formation; Shrinkage from bridging fibrosis.").

[31] TVT IFU from Ethicon website (http://www.ethicon.com/healthcare-professionals/ifu).

[32] ETH.MESH.03910418 (11/25/02 internal e-mail regarding, inter alia, mesh shrinkage in TVT) – "As we discussed the shrinkage rate is influenced by many parameters as the degree of fibrotic reaction is dependent on the mesh material/weave/width etc. I remember that Axel [Arnaud, Ethicon‟s European Medical Director] was using 30% shrinkage as a rule of thumb…."); ETH.MESH.05246528 (3/10/05 report discussing areas impacting clinical outcomes with mesh) – "Tissue contraction (20-40%), Scar formation = recurrence or dyspareunia…Erosions - potentially address through technique."); ETH.MESH.04020138 (4/13/05 e-mail from Ethicon engineer) – "In pelvic floor repair even with the PSM, we have seen some scar contracture which translates into procedural complications… [S]urgeons who are our consultants on the ProLift product are asking for a mesh which is better than PSM in this area." (Id.). "The surgeons attribute these conditions [recurrence of prolapse, pain, stiffness, erosion and discomfort during sex] to scar contracture."); ETH.MESH.05243265 (1/24/06 e-mail discussing meeting with consulting physicians in Europe) – "Their [physicians‟] main concern is the believe that the Prolene Soft material over time contracts. Thus creating the potential for failures and/our erosions."); ETH.MESH.03906525 (1/27/06 internal PowerPoint by Ethicon‟s European Medical Director), Slide 30 ("Mesh must not shrink. Rationale: to preserve the vaginal anatomy and to avoid recurrences. Theory: The scar tissue naturally shrinks up to 70% in the wound area during the healing process. Physiological wound contraction increases with the extent of inflammation. Shrinkage could be minimized by reducing the inflammatory reaction: well tolerated material, large pores."); ETH.MESH.00870466 (6/2/06 Expert Meeting Memo) ("Shrinkage of 20% means reduction of mesh area to 64%."); ETH.MESH.10511708 (12/12/06 internal R&D PowerPoint "State of Knowledge in Mesh Shrinkage") – "„Shrinking meshes‟ are a topic of discussion and concern among hernia surgeons. It is believed that mesh shrinkage may lead to patients' discomfort, chronic pain or hernia recurrence…. Mesh shrinkage was evaluated at different time points and the reduction of the calculated area was 12% at one month, 24% at 3 months, 29% at 6 month and 34% at 12 month. [citing 2006 literature]"); ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) ("Polypropylene meshes might not be improvable in terms of shrinkage, we may need a completely new material… Unmet clinical needs: No shrinkage/no long term contraction… Severe contraction → Dyspareunia → sexual function ↓."); ETH.MESH.01818382 (12/20/07 Ethicon Mesh Contraction preclinical study) (27% shrinkage (measured radiographically) and 23% (measured by image analysis), as well as fibrotic bridging, folding, rippling and distortion, for Prolene Soft in the subcutaneous model after 13 weeks implantation); ETH.MESH.13375497 (10/1/08 internal PowerPoint) – "Issues with Polypropylene Mesh…"); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering."); ETH.MESH.02227282 (11/14/09 PowerPoint), p. 7 – "Folding of mesh is one cause for erosion and pain."); ETH.MESH.05479695 (Nov. 3-4, 2010 Mesh and Textile Summit PowerPoint) – "There is no place for a „Heavyweight Mesh‟ in modem pelvic floor repair… Polypropylene Mesh – Small pore size (<1 mm)… Issues with small pore meshes –…Increased inflammatory response results in rigid scar plate formation – Scar plate responsible for shrinkage of mesh up to 40% [citing published literature from 2002 and 2004]").

[33] ETH.MESH.00870467 (6/20/06 notes re: Ethicon Expert Meeting) – "Optimum pore size is material dependent (critical pores size; at least 1-2mm), scar formation a combination of pore size, surface area, polymer…. Small pores: interconnection between mesh pores due to fibroses leading to mesh shrinkage…. Tension of the mesh changes pore size → change in elasticity…."); ETH.MESH.01752532 (9/18/06 internal memo) – "Large-pore mesh integrates in a loose network of perifilamentous fibrosis with fat tissue present in between. In contrast, the small-pore mesh incorporates entirely in perifilamentary granulomas and scar tissue, which bridged the whole pore diameter of less than 1 mm [citing literature from 2002]. It appears that the greater distance between pores resists the ability of „bridging fibrosis" …, contributing to improved compliance and theoretically less passive compression or shrinkage of the biomaterial…. The applicability of meshes as a prosthesis in the pelvic floor region is dependent on various mesh properties. A suitable mesh should offer a pore size >1mm and feature lightweight properties to avoid the occurrence scar plate formation."); ETH.MESH.10511708 (12/12/06 internal R&D PowerPoint "State of Knowledge in Mesh Shrinkage") – "The tissue incorporation of a mesh prosthesis is proportional to its pore size, since macroporous structures are required for the entrance of macrophages, fibroblasts, blood vessels and collagen fibers. Larger pores allow for faster ingrowth into the mesh, which results in less contraction. On the other hand, the small pore mesh incorporates entirely in perifilamentary granulomas and scar tissue, which bridge the whole pore diameter. This so called „fibrotic bridging" is a phenomenon that is believed to be closely related to mesh shrinkage and is usually observed in all mesh modifications with pore sizes of less than 1 mm…. Conclusion - the „ideal mesh": Taking all these abovementioned facts into consideration, the ideal mesh could appear as follows:… pore size > 1mm."); ETH.MESH.01782867 (2/24/07 internal PowerPoint "Factors related to mesh shrinkage"), p. 6 – "Small porous meshes (<1 mm) lead to „fibrotic bridging" → increased shrinkage…. Pore size – The tissue incorporation of a mesh prosthesis is proportional to its pore size… Larger pores allow for faster ingrowth into the mesh, which results in less contraction. On the other hand, the small pore mesh incorporates entirely in perifilamentary granulomas and scar tissue, which bridge the whole pore diameter. This so called „fibrotic bridging is a phenomenon that is believed to be closely related to mesh shrinkage and is usually observed in all mesh modifications with pore sizes of less than 1mm."); ETH.MESH.02588170 (1/22/08 internal memo regarding desired mesh design features) – "4. shrinkage/stiffening 1. pore size > 3 mm 2. pore size > 1 mm under stretch (mesh + stress shielding component only) • stress shielding of mesh implant (duration < 7d) (Abramov 2006).…Mesh pore size varies under the impact an applied load."); ETH.MESH.13375497 (10/1/08 internal PowerPoint) – "Issues with Polypropylene Mesh • Excessive foreign body reaction • Chronic inflammation…• Scar plate formation • Stiffness…• „Shrinkage" 20-40%.").

[34] ETH.MESH.10663008 (5/31/05 internal e-mail including mesh comparison chart showing Prolene mesh has pore size "<1" mm^2); ETH.MESH.02183202 (internal mesh comparison chart showing pore size of Prolene mesh ranging from ".16 - 1" mm).

[35] ETH.MESH.00870466 (6/20/06 notes re: Ethicon Expert Meeting) – "Meshes can cause Nerve damage due to mechanical irritation (mesh bears on nerve)…. Vaginal pain after implantation of meshes is rare, but feared, since there is not real treatment option"); HMESH_ETH_01800994

(10/11/06 internal e-mail chain discussing mesh pain/shrinkage literature) ("The take home message from the article was that chronic pain can be associated with placement of a mesh device…. [The author] continues to point out that neuropathy-related complaints after intraoperative damage of nerve fibers is associated with pain immediately after surgery, however, the onset of chronic pain as a consequence of the „foreign body reaction" is typically more than one year after the hernia repair. He goes on to point out that patients that reported chronic pain demonstrated nerve fibers and fascicles in the interface of the mesh upon examination upon removal."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering.").

[36] ETH.MESH.08167452 (10/3/00 internal e-mail in response to e-mail from physician consultant regarding instructions for TVT removal procedure) – "Theoretically, I can envisage no need for TVT explant. And I agree…that if we, in any way, publish such an information, we start giving the reason to believe that explant of the TVT may be needed in some circumstances. Frankly, I do not want to dig my own grave...!"…"In my opinion, we must be very careful in avoiding 'overinformation'").